IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

NELLCOR PURITAN BENNET, INC, et al

Plaintiffs,

v

PORTEX, INC, et al

Defendants.
_____/

No C 04-1934 VRW

ORDER

On February 11, 2005, the court held a claim construction hearing pursuant to Markman v Westview Instruments, Inc, 517 US 370 (1996). Based on the parties' arguments at the hearing and their submissions to the court, the court issues the following claim construction order.

There are three patents-in-suit, all relating to inventions in the field of endotracheal catheters (used, for example, in resuscitation) and associated devices to determine whether the catheter has been correctly inserted. For ease of cross-reference to the parties' submissions, the court discusses

the patents and construes their terms in the same sequence as the patents appear in the parties' submissions. As the court writes principally for the parties, it will not discuss the details of the inventions or define terms well-known to those skilled in the art, except as is necessary to construe the claims of the patents.

I

United States Patent No 4,879,999 (the "'999 patent"), granted to Basil C Lehman et al on November 14, 1989, discloses "an endotracheal device * * * with a colorimetric carbon dioxide indicator." '999 patent, Abstract. The device indicates "proper intratracheal placement * * * by detecting * * * the presence of carbon dioxide in expired air passing through the device." Id. Plaintiffs assert that defendants infringe claims 3, 6-10, 13-17, 20-23, and 25 of the '999 patent. Doc #45 at 1.

United States Patent No 5,166,075 (the "'075 patent"), granted to Carl G Fehder on November 24, 1992, discloses a method for "determining whether respiratory gas is present in a gaseous sample." '075 patent, Abstract. The method functions by bringing the gaseous sample into contact with "an indicator which yields an indication within a diagnostically effective period of time of the presence * * * of carbon dioxide in concentration of at least 2%." Id. Additionally, the indicator provides an indication of "the presence of carbon dioxide in a sample of ambient air * * * delayed beyond a predetermined period of time." Id. Plaintiffs assert that defendants infringe claims 1, 2, 4, 6-8, 15, 18-22, 24, and 25 of the '075 patent. Doc #45 at 1.

US Patent No 5,179,002 (the "'002 patent"), granted

January 12, 1993, also to Carl G Fehder, describes an apparatus "for determining whether respiratory gas is present in a gaseous sample." '002 patent, Abstract. An indicator "yields an indication within a diagnostically effective period of time of the presence of * * * carbon dioxide in concentrations of at least 2% while an indication of * * * carbon dioxide or other trace acidic gas in * * * ambient air is delayed." Id. Plaintiffs assert that defendants infringe claims 1, 2, 4-9, 12, 22-24, and 25 of the '002 patent. Doc #45 at 1.

II

The construction of patent claims is a question of law to be determined by the court. Markman v Westview Instruments, Inc, 517 US 370 (1996). The goal of claim construction is "to interpret what the patentee meant by a particular term or phrase in a claim." Renishaw PLC v Marposs SpA, 158 F3d 1243, 1249 (Fed Cir 1998). In determining what a patentee meant by a term or phrase, the court looks first to the claim itself.

> The claims of the patent provide the concise formal definition of the invention. They are the numbered paragraphs which "particularly [point] out and distinctly [claim] the subject matter which the applicant regards as his invention." 35 USC § 112. It is to these wordings that one must look to determine whether there has been infringement. Courts can neither broaden nor narrow the claims to give the patentee something different than what he has set forth. No matter how great the temptations of fairness or policy making, courts do not rework claims. They only interpret them.

EI Du Pont de Nemours & Co v Phillips Petroleum Co, 849 F2d 1430, 1433 (Fed Cir 1988).

"The claims define the scope of the right to exclude; the claim construction inquiry, therefore, begins and ends in all cases

with the actual words of the claim." Renishaw, 158 F3d at 1248. "The words used in the claim are viewed through the viewing glass of a person skilled in the art." Brookhill-Wilk 1, LLC v Intuitive Surgical, Inc, 326 F3d 1215, 1220 (Fed Cir 2003) (citing Tegal Corp v Tokyo Electron Am, Inc, 257 F3d 1331, 1342 (Fed Cir 2001)). "Absent a special and particular definition created by the patent applicant, terms in a claim are to be given their ordinary and accustomed meaning." York Prods, Inc v Central Tractor Farm & Family Ctr, 99 F3d 1568, 1572 (Fed Cir 1996). The court may, if necessary, consult a variety of sources to determine the ordinary and customary meaning of a claim term, including the claim terms themselves, dictionaries, the written description, the drawings and the prosecution history, if in evidence. Brookhill-Wilk 1, 326 F3d at 1220. "Such intrinsic evidence is the most significant source of legally operative meaning of disputed claim language." Vitronics Corp v Conceptronic, Inc, 90 F3d 1576, 1582 (Fed Cir 1996). With respect to dictionary definitions, "[i]f more than one dictionary definition is consistent with the use of the words in the intrinsic record, the claim terms may be construed to encompass all such consistent meanings." Texas Digital Systems, Inc v Telegenix, Inc, 308 F3d 1193, 1203 (Fed Cir 2002).

The court begins its construction of claim terms by consulting intrinsic evidence of the meaning of disputed claim terms, which includes the claims, the specification and the prosecution history (if in evidence). Lacks Industries, Inc v McKechnie Vehicle Components USA, Inc, 322 F3d 1335, 1341 (Fed Cir 2003) (citation omitted). "If upon examination of this intrinsic evidence the meaning of the claim language is sufficiently clear,

resort to 'extrinsic' evidence, such as treatises and technical references, as well as expert testimony when appropriate, should not be necessary." Digital Biometrics, Inc, v Identix, Inc, 149 F3d 1335, 1344 (Fed Cir 1998). "[I]f after consideration of the intrinsic evidence, there remains doubt as to the exact meaning of the claim terms, consideration of extrinsic evidence may be necessary to determine the proper construction." Id.

"[A] court may constrict the ordinary meaning of a claim term in * * * one of four ways[:]" (1) "if the patentee acted as his own lexicographer and clearly set forth a definition of the disputed claim in either the specification or prosecution history;" (2) if the intrinsic evidence shows that the patentee distinguished the term from prior art on the basis of a particular embodiment, expressly disclaimed subject matter, or described a particular embodiment as important to the invention; (3) "if the term chosen by the patentee so deprives the claim of clarity as to require resort to other intrinsic evidence for a definite meaning; and (4) "if the patentee phrased the claim in step- or means-plus-function format," then "a claim term will cover nothing more than the corresponding structure or step disclosed in the specification, as well as equivalents thereto * * *." CCS Fitness, Inc v Brunswick Corp, 288 F3d 1359, 1366-67 (Fed Cir 2002) (internal citations and quotation marks omitted).

Limitations from the specification, such as from the preferred embodiment, cannot be read into the claims absent an express intention to do so. Teleflex, Inc v Ficosa North Am Corp, 299 F3d 1313, 1326 (Fed Cir 2002) ("The claims must be read in view of the specification, but limitations from the specification are

not to be read into the claims."). But "a construction that excludes a preferred embodiment 'is rarely, if ever, correct.'" C R Bard, Inc v United States Surgical Corp, 388 F3d 858, 865 (Fed Cir 2004) (citing Vitronics, 90 F3d at 1583).

"A claim limitation that actually uses the word 'means' invokes a rebuttable presumption that [35 USC] § 112 P 6 applies. By contrast, a claim term that does not use 'means' will trigger the rebuttable presumption that § 112 P 6 does not apply." CCS Fitness, Inc v Brunswick Corp, 288 F3d 1359, 1369 (Fed Cir 2002). Furthermore, the "presumption flowing from the absence of the term 'means' is a strong one that is not readily overcome." Lighting World, Inc v Birchwood Lighting, Inc, 382 F3d 1354, 1358 (Fed Cir 2004).

With these legal principles in mind, the court now turns to the construction of the disputed claim language of the three patents-in-suit.

III

The '999 Patent

A

The parties parse the elements of '999 claims differently, making it difficult directly to compare their proposed term constructions. Claim 3 is illustrative of the parties' main disagreements:

> 3. An endotracheal device comprising:
>
> (a) a first tubular housing having a first and second end, the first end adapted for insertion into a patient's trachea and the second end

> adapted for placement external of the patient, the first tubular housing defining lumen means therethrough from the first end to the second end;
>
> (b) a second housing attached to the second end of the first tubular housing, said second housing defining lumen means therethrough communicating with and forming an extension of the lumen means of the first housing, the lumen means of both housings for allowing bidirectional passage of air into and out of the patient to ventilate the patient's lungs; and
>
> (c) colorimetric carbon dioxide indicator means mounted within the lumen means of said second housing for determining the presence of carbon dioxide therein while still permitting unimpeded bidirectional flow of air through the housings to ventilate the lungs of the patient.

1. a first tubular housing

The parties do not dispute the construction of this term. Accordingly, the court declines to construe this term.

2. lumen means therethrough from the first end to the second end

The parties disagree on how to define the lumen means-plus-function element of the asserted claims. Both parties agree that the "lumen means" element of claim 3 is governed by 35 USC § 112, ¶6. Doc #60 at 15, Doc #65 at 2. Therefore, the court must determine (1) the claimed function, and (2) the corresponding structures recited within the patent specification that provide a

means for performing the claimed function. See Kemco Sales, Inc v Control Papers Co, Inc, 208 F3d 1352, 1361 (Fed Cir 2000).

The first use of the term "lumen means" is contained in clause (a) of claim 3 as shown above. "Therethrough" refers to the first housing and indicates that the lumen proceeds from the first end of the first housing through the second end of the first housing. It is important to note that although the means term is used in this clause, a function has not yet been defined for the means and as such the means-plus-function element is incomplete for analysis at this point in the claim.

3. a second housing

Plaintiffs propose that "a second housing" be construed as "a housing, formed of one or more components, that need not be in tubular configuration." Doc #45 at 7. Defendants argue that a second housing should be construed as "a single housing," and further argue that because the second housing defines a lumen means which is an "extension" of the lumen means of the first housing, "the combination must have a second end so that the combination is a true extension of the first housing." Doc #68 at 3.

Defendants incorrectly attempt to add an additional limitation in the form of a second end on the second housing. Claim 3 recites the second housing without reference to any ends. The plain meaning of "extension" does not require an extension to be in the exact form of the shape it extends. Similarly, plaintiffs' attempt to broaden the definition of "housing" to encompass housings made of one or multiple components is unwarranted; the claim literally reads upon "a second housing."

Whether the second housing can be made of more than one component is an issue for the doctrine of equivalents, not claim construction. See Dawn Equipment Co v Kentucky Farms, 140 F3d 1009, 1016 (Fed Cir 1998) (explaining that the trier of fact applies the "function-way-result" test and the "insubstantial differences test" to determine whether a claim is infringed under the doctrine of equivalents). Thus, the court construes "second housing" to mean a single housing, that need not be in tubular configuration.

4. attached

Plaintiffs argue that "attached" should be construed to mean "connected directly or through one or more intermediate structures." Doc #45 at 7. Defendants propose "connected directly." Again, plaintiffs attempt to enlarge the scope of the claim language to bring the doctrine of equivalents into literal claim interpretation. After reading the term in light of the specification and claim language, the court construes "attached" as connected directly. Nowhere in the specification are the housings described as "connected through one or more intermediate structures." Therefore, whether claim 3 reads upon a structure connected through one or more intermediate structures is an issue to be considered under the doctrine of equivalents by the trier of fact, not by the court in claim construction. Dawn Equipment, 140 F3d at 1016.

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5. lumen means therethrough communicating with and forming an extension of the lumen means of the first housing

The second use of the term "lumen means" is contained in clause (b) of claim 3 as shown above. In this clause, "therethrough" refers to the second housing, which is not limited by any language requiring either a first end or a second end. This clause adds to the definition of the lumen means by showing that it extends through the first housing and into the second housing. Although the lumen means is further defined by this language, a function has not yet been identified at this point in the claim, and as such the means-plus-function element is incomplete for analysis as a whole.

6. lumen means of both housings for allowing bidirectional passage of air into and out of the patient to ventilate the patient's lungs

This language defines the function of the lumen means and is the crux of parties' dispute. The court is tasked with (1) identifying the claimed function of the means, and (2) identifying the corresponding structures in the specification that perform the claimed function. Kemco Sales, Inc v Control Papers Co, 208 F3d 1352, 1361 (Fed Cir 2000). Accordingly, to be claimed in claim 3, the corresponding structures of the lumen means must perform the function of "allowing bidirectional passage of air into and out of the patient to ventilate the patient's lungs."

Plaintiffs argue for a plain meaning construction of the function. Defendants propose a construction that removes the permissive word "allowing" and requires that the lumen means have a second end. Doc #68 at 6. As discussed above, neither a first nor

a second end of the second housing is recited in the claim and therefore, the court rejects defendants' arguments regarding the nature of the lumen means "extension" through a second end of the combination. Defendants additionally argue that because the patent examiner required an amendment to recite that the lumen means of "both housings allow the bidirectional flow of air," the plaintiffs are barred by prosecution history estoppel from claiming all of the disclosed embodiments. Doc #68 at 6. Specifically, defendants argue that this amendment requires the corresponding structures to be limited to those describing "one continuous lumen means," and therefore, the embodiment depicted in figure five is excluded. Id at 6-7.

But it is a non sequitur to argue that if (1) both housings allow bidirectional flow, and (2) the lumen means of the second housing is an extension of the lumen means of the first housing; then the extension through the second housing must be in the same direction, shape and manner as the lumen means of the first housing so as to require bidirectional flow through both housings. "Allowing" is a permissive term, and the plain meaning of the word and the patent specification lead the court to accept the plain meaning construction. Therefore, the court adopts plaintiffs' proposed construction and construes the function of the corresponding structures to be "allowing bidirectional passage of air into and out of the patient to ventilate the patient's lungs."

Plaintiffs propose that this means-plus-function clause be construed so that the corresponding structures of the lumen means of both housings are "the hollow bodies of the first and second housings described and illustrated in the specification, and

their equivalents that define one or more luminal air flow paths or channels." Doc #45 at 9. Defendants propose that "lumen means" as recited in claims 3, 6, 7, 10, 13, 15, 17, 20-22 and 25 be construed as "limited to the spaces defined by the rigid structures described in the specification of the '999 patent" and further modified by the limitations in each claim. Doc #60 at 15. Aditionally, defendants reiterate their argument that "both housings" in combination must be limited to structures with a first end and a second end in order to allow bidirectional passage of air, which, since the housings define the lumen means, requires that it have a first and second end as well. Id at 17.

In construing a § 112, ¶6 claim, a court may not import functional limitations that are not recited in the claim, or structural limitations from the written description that are unnecessary to perform the claimed function. Wenger Manufacturing Inc v Coating Machinery Systems, Inc, 239 F3d 1225, 1233 (Fed Cir 2001). Defendants' construction attempts to introduce an unclaimed limitation to the structures defined by the lumen means in the form of the adjective rigid. Similarly, defendants' construction attempts to require the limitation of a second end on the second housing, which is unsupported by the claim language.

Plaintiffs' proposed construction, however, proposes the introduction of additional language, so that the lumen means explicitly defines "one or more luminal air flow paths or channels." Doc #45 at 9. Claim 3 contains no mention of air flow paths or channels, and thus plaintiffs' construction impermissably introduces unclaimed structure to clarify the means-plus-function element. Therefore, the court construes the corresponding

structures of the "lumen means" to include all structures described in the patent specification going through a first end of a first housing through a second end of the first housing and communicating with and extending through a second housing -- regardless of air flow paths or channels.

In sum, the court construes the lumen means-plus-function element of claim 3 to read upon: all structures described in the specification of the '999 patent (1) defined by going through a first end of a first housing through a second end of the first housing, and communicating with and extending through a second housing (2) that perform the function of "allowing bidirectional passage of air into and out of the patient to ventilate the patient's lungs."

7. colorimetric carbon dioxide indicator means mounted within the lumen means of said second housing

Like the lumen means in clauses (a) and (b), the indicator means-plus-function element is incomplete for analysis until its function has been identified. In light of the corresponding structures that perform the function identified later in the claim, this clause limits the indicator means of claim 3 to those structures "mounted within the lumen means of the second housing." Defendants, again relying on a definition of lumen means that requires a second end and bidirectional flow through all sections, argue that certain embodiments shown in the '999 figures are not claimed in claim 3. As addressed above, this argument is in error. Therefore, "mounted within the lumen means of the second housing" is simply construed as the plain meaning of "mounted

within" in light of the court's constructions of second housing and lumen means above.

8. for determining the presence of carbon dioxide therein

This clause defines the function performed by the colorimetric carbon dioxide indicator means ("indicator means"). The parties do not argue over the function itself. Rather, they disagree about which corresponding structures disclosed in the specification are capable of performing this function, i e, which structures determine the presence of carbon dioxide within the lumen means of the second housing. Plaintiffs argue that the indicator means is described by the specification as "hydrazine and other disclosed compounds that cause a pH change * * * in combination with a colorimetric pH indicator." Doc #65 at 8. Defendants argue that the indicator means should be "limited to an indicator substance in a solid support where the indicator substance is limited to the carbon dioxide indicator composition disclosed in the specification, namely, hydrazine, or its equivalents." Doc #60 at 20.

Defendants' attempt to introduce the "in a solid support" limitation to the claim is in error. The court will not introduce an unclaimed limitation into a means plus function claim, even if the limitation is recited in the specification. Wenger Manufacturing, 239 F3d at 1233. Therefore, to the extent that the patent specification describes corresponding structures capable of performing the claimed function within the limitations of the claim, those corresponding structures are claimed by claim 3, whether or not they are disclosed as being within a solid support.

Defendants attempt to limit the corresponding structures of the indicator means to hydrazine on the basis that the inventors used hydrazine in the actual reduction to practice. Doc #60 at 20. Defendants argued at oral argument that in order to perform the function of the means-plus-function clause, the corresponding structure must "work." Plaintiffs argued that actual reduction to practice is irrelevant because everything disclosed in the patent application is treated as constructively reduced to practice, and as such, it is a proper subject matter for corresponding structures. Plaintiffs also properly argued that defendants' actual-reduction-to-practice argument is an invalidity argument (i e, if a corresponding structure is incapable of performing the claimed function, then the claim is invalid under 35 USC § 112, ¶1 because it fails to enable one skilled in the art to practice the invention), which is not for the court to consider during claim construction.

Accordingly, the court adopts plaintiffs' contruction and construes "colorimetric carbon dioxide indicator means" to cover combinations of (1) a compound disclosed in the patent specification for causing a pH change with (2) a colorimetric pH indicator disclosed in the patent specification for determining the presence of carbon dioxide within the lumen means of the second housing.

9. <u>while still permitting unimpeded bidirectional flow of air through the housings to ventilate the lungs of the patient.</u>

Defendants argue, based on dictionary definitions and prosecution history estoppel, that "unimpeded" should be construed

as "unrestricted." Doc #60 at 18; Doc #68 at 8. Defendants also point to a dictionary defintion in support of this construction, where impede means "to interfere with or get in the way of the progress of," or is a synonym for "hinder." Doc #60, Ex 13.

Defendants' strongest patent prosecution history estoppel argument is based upon the patent examiner's reexamination analysis of the term "impeded" as it was used to distinguish claims from the prior art. Doc #61, Ex 25 at 2. Pursuant to 35 USC § 302, ICOR AB, a Swedish corporation and apparently a non-party to this litigation, requested a reexamination of the '999 patent in light of several previously unconsidered references. Doc #61, Ex 23. In its request for reexamination, ICOR AB argued for roughly the opposite construction to defendants' proposed construction, asking the examiner to find that this clause was essentially a non-limitation because "no patient can breath through an impediment." In response to this argument, the examiner considered the Adriani reference, which described soda lime crystals impregnated with dyes that changed colors in response to pH changes within a to-and-fro cannister through which a patient under anesthesia breathed. File History SN 90/003,808, at DFH00835-842.

In confirming patentability after reexamination, the examiner noted:

> The claims do not require the patient breath[e] through a[n] impediment or that merely bidirectional flow be permitted but rather to permit unimpeded flow. Bidirectional flow may still exist where there is an impediment but be retarded or hindered thereby, i.e. a lesser degree of bidirectional flow exists or impeded bidirectional flow exists. Requestor's interpretation of "impeded", i.e. not allowing any flow, and thus the converse term "unimpeded" differs in scope from the broadest

reasonable interpretation of such terms."

Doc #62, Ex 25 at 2.

In other words, in confirming patentability of the '999 patent over the prior art submitted in the reexamination request, the examiner found that this limitation's recitation of "unimpeded" meant the bidirectional flow must be "unrestricted" or the converse of "not allowing any flow." Id. This determination allowed the patent claims to remain patentable in light of the Adriani reference whereby the airflow through the canister resulted in "impedance to the flow of gases" both from the soda lime granules in the inhaler as well as from the valves and tubes causing "turbulent flow and friction." DFH000840. In light of the dictionary definitions submitted by defendant and the plain meaning of the claim language, the court agrees with the examiner's construction of the word "unimpeded."

While the examiner's reexamination construction is instructive on the interpretation of "unimpeded," it is not controlling. This is not a case of prosecution history estoppel, because here, the patentee did not "forgo an appeal and submit an amended claim, [which was] taken as a concession that the invention as patented does not reach as far as the original claim." Festo Corp v Shoketsu Kinzoku Kogyo Kabushiki Co, 535 US 722, 734. Defendants correctly argue that "claims may not be construed [by the inventor] one way in order to obtain their allowance and in a different way against accused infringers." Doc #60 at 19. This principle applies with equal force to arguments made by a patentee to sustain the patentability of claims during reexamination. Spectrum International v Sterilite Corp, 164 F3d 1372, 1379.

But the patentee is under "no obligation to respond to an examiner's statement of Reasons for Allowance, and the statement of an examiner will not necessarily limit a claim." Eolas Techs, Inc v Microsoft Corp, -- F3d -- , --; 2005 US App LEXIS 3476, 31 (Fed Cir 2005) (quoting ACCO Brands, Inc v Micro Security Devices, Inc, 346 F3d 1075, 1078 (Fed Cir 2003)). In the case at bar, defendants have not shown that patentees made a limitation in acceptance of the examiner's reexamination construction or advanced an argument to overcome the prior art. In fact, the reexamination history submitted to the court does not contain any arguments advanced by the patentee in response to ICOR's ex parte reexamination notice. Doc #62, Ex 23-25; File History SN 90/003,808 binder.

In contrast to reexamination, the patentee did assert arguments to the patent office during ordinary prosecution of this claim limitation. Those arguments show that the patentee intended this limitation to mean that the bidirectional flow of air to the patient must be unimpeded. Doc #61 Ex 19 at 13. But the inventor's arguments also make it clear that the limitation was meant to require unimpeded airflow only through the bidirectional pathway

to the patient, and did not necessarily apply to other airflow:

> In the same fashion, while flow may be partially impeded through the side-arm 24 of the figure 5 embodiment (e g, when cap 40 is in place), in no way is the bidirectional flow of air to the patient impeded, as represented by flow through the primary luminal path 6.

Id.

Therefore, the court adopts defendants' construction of the term "unimpeded," but interprets the entire limitation in light

of the patent prosecution history and specification such that it is only the bidirectional passage of air to the patient that must be unrestricted.

B

At oral argument, the parties agreed that construing claim 3 would resolve the majority of issues relating to the '999 patent. Plaintiffs' opening brief argues for construction of three terms outside of claim 3 of the '999 patent: "indicator substance" as it first appears in claim 7; "a passage therethrough which defines the housing lumen means" as it first appears in claim 8; and "within the passage of the connector" as it first appears in claim 8.

1. indicator substance

Defendants argue that "indicator substance," as it first appears in claim 7, should be construed as a means-plus-function element. Doc #68 at 9. Furthermore, defendants argue that the corresponding structures of the indicator substance should not encompass all indicators listed in the specification, but should instead be limited to "hydrazine, or its equivalents." Doc #68 at 9. Plaintiffs' proposal appears to accept that "indicator substance" should be construed as a means-plus-function element because it is written in terms of "the structures and materials described in the specification * * * that perform the function of providing a visually observabe color change in the presence of air that contains carbon dioxide in a concentration that is normally present in expired respiratory gas." Doc #45 at 15.

The fundamental difference between the proposed constructions is that plaintiffs' proposal both defines the function performed by the indicator substance and includes all corresponding structures listed in the patent specification that perform that function, while defendants' construction neglects to define the function and attempts to limit the corresponding structures to hydrazine or its equivalents.

Defendants do not challenge the function proposed by plaintiffs, and they summarily state that the indicator chemistry must be limited to hydrazine or its equivalents, the same argument that the court has rejected in construing "for determining the presence of carbon dioxide therein." Doc #68 at 9. Defendant further argues that "indicator substance" should be limited to "an indicator substance in a solid support." Doc #60 at 20. This interpretation directly contradicts the language of claim 7, which states that the indicator means "comprises a colorimeteric carbon dioxide indicator substance and solid support means." It is illogical to interpret "indicator substance" as requiring a solid support when the claim explicitly lists the element of a solid support on its own.

Plaintiffs' proposal contains the language, "and their equivalents." Doc #45 at 15. It is well settled that "for the court to find infringement the plaintiff must show the presence of every element or its substantial equivalent in the accused device." Lemelson v United States, 752 F2d 1538, 1551 (Fed Cir 1985). If necessary, the finder of fact will consider the doctrine of equivalents as it pertains to all claims; accordingly, the court will not construe any terms by using unneccessary language

regarding equivalents.

The court adopts plaintiffs' construction with the exception of the equivalents language and construes "indicator substance" as "the structures and materials described and illustrated in the specification that perform the function of providing a visually observable color change in the presence of air that contains carbon dioxide in a concentration that is normally present in expired respiratory gas."

2. a passage therethrough which defines the housing lumen means, and the indicator means is mounted within the passage of the connector.

Plaintiffs propose that "passage," as it first appears in claim 8, be construed as "one or more passages that extend through the tubing connector and define the lumen means of the second housing." Doc #45 at 15. Defendants argue that "a passage," when read in light of the rest of the claim language -- particularly, "within the passage" -- must be limited to a single passage. Doc #68 at 9-10. Defendants' attempt to limit claim 8 to read upon only those second housings in which the tubing connector has one and only one passage therethrough is misplaced. Nothing in the claim language suggests this limitation.

The reference to "the passage" simply requires that the indicator means is mounted within the passage that satisfies the "passage therethrough which defines the housing lumen means" requirement of this claim; it says nothing about excluding alternate embodiments that otherwise meet all of the claim elements. Accordingly, the court construes claim 8 to read upon (1) any endotracheal device read upon by claim 3 (2) where the

second housing includes a tubing connector having a passage therethrough which defines the housing lumen means (as construed above) (3) and the indicator means (as construed above) is mounted within the passage of the connector.

III

The '075 Patent

The parties' central disagreement about the construction of claims in the '075 patent concerns water, and the terms used to describe its presence in the claimed invention, an apparatus for determining whether respiratory gas is present in a gaseous sample. Terms construed for the '075 patent have the same construction in the '002 patent unless otherwise stated. Claim 1 is illustrative:

> A method for determining whether a gaseous sample contains a predetermined concentration of carbon dioxide, comprising the step of:
>
> contacting the gaseous sample with a dry reagent detector comprising a carrier having an aqueous indicating composition applied thereto for providing an indication of the presence of the predetermined concentration of carbon dioxide in the sample within a diagnostically effective period of time when the carbon dioxide concentration in the sample is at least about 2% and providing said indication after about ten minutes when the carbon dioxide concentration in the sample is about 0.03%.

1. dry reagent detector

The parties agree that the term "dry reagent detector," which first appears in claim 1, includes detectors that contain some water. Doc #68 at 11, n5. Therefore, the court adopts plaintiff's construction, "a detector having an immobilized reagent with excess liquid removed but which may contain some water." Doc

#45 at 19.

2. aqueous indicating composition

Plaintiffs argue for the construction of "an indicating composition containing some water." Doc #45 at 19. Defendants argue that this term refers to "an indicator composition that functions in liquid water." Doc #68 at 12. Both parties dedicated a considerable portion of their briefing and oral argument to the definition of the term "aqueous." In doing so, both parties pointed to relevant portions of the specification, expert testimony and dictionary definitions in support of their proposed constructions. Markman Hearing, plaintiffs' slides 25-27; defendants' slides 49-54.

Plaintiffs' construction, as the broader of the two, does not exclude any of the dictionary definitions, expert testimony or portions of the specification cited by defendants. On the other hand, defendants' construction requires limitation of the dictionary definition submitted by plaintiff and discounts portions of the testimony of the named inventor. Neither party has shown that the other party's construction directly conflicts with the specification or the prosecution history.

The Federal Circuit has held that "[i]f more than one dictionary definition is consistent with the use of the words in the intrinsic record, the claim terms may be construed to encompass all such consistent meanings." Texas Digital Systems, Inc v Telegenix, Inc, 308 F3d 1193, 1203 (Fed Cir 2002). On this legal principle alone, the court would adopt plaintiffs' proposed construction. Additionally, defendants' use of "functions in"

imports a limitation to the claim language that is neither in the plain language meaning of the claim, nor found in any of the submitted dictionary definitions. Accordingly, the court adopts plaintiffs' proposition and construes aqueous indicating composition as "an indicating composition containing some water."

3. and providing said indication after about ten minutes when the carbon dioxide concentration in the sample is about 0.03%

Defendants argue that the plain meaning construction of "after about ten minutes" is equivalent to "at or about ten minutes." Doc #68 at 14. Plaintiffs contend that the plain meaning of "after" is not equivalent to "at or about." Doc #45 at 20. The prosecution history shows that the patent examiner requested an examiner's amendment to change the claim language from "but not providing said indication for more than about ten minutes" to its present form. Doc #62, Ex 27 at 2, Exs 28-29. The patentee had a right to object to the examiner's requested amendment and appeal the examiner's rejection but opted instead to accept the amendment so that the claim would be allowed. Id. When a patentee forgoes the option to appeal and instead submits an amended claim, it is "taken as a submission that the invention as patented does not reach as far as the original claim." Festo Corp v Shoketsu Kinzoku Kogyo Kabushiki Co, 535 US 722, 734 (2002).

Plaintiffs' construction impermissably attempts to recapture the open-ended limitation that was given up during patent prosecution in order to get the claims in a condition for allowance. Accordingly, the court adopts defendants' proposal and construes "after about ten minutes" to mean "at or about ten

minutes."

4. a dried non-volatile indicating element

Defendants contend that "indicating element," as it first appears in asserted claim 18, must be construed as a means-plus-function element under § 112, ¶6 because the indicating element is described "exclusively by the function it performs." Doc #68 at 11. The absence of the word "means" in a claim element creates a presumption that the element should not be construed under 35 USC § 112, ¶6. Linear Technology Corp v Impala Linear Corp, 379 F3d 1311, 1319 (Fed Cir 2004). To overcome this presumption, the proponent of interpretation under § 112, ¶6 has the burden of showing that the claim "fails to recite sufficiently definite structure or recites a function without reciting sufficient structure for performing that function." CCS Fitness Inc v Brunswick Corp, 288 F3d 1359, 1369 (Fed Cir 2002) (internal citations omitted). Furthermore, this presumption is "a strong one that is not readily overcome." Lighting World, Inc v Birchwood Lighting Inc, 382 F3d 1354, 1358 (Fed Cir 2004).

Defendants assert that it is "impossible for one ordinarily skilled in the art to identify what materials are being claimed." Markman Hearing, defendants' slide 72. However, defendants do not point to any evidence, expert testimony or otherwise, in support of that assertion. Doc #60 at 22-23, Doc #68 at 11. Instead, defendants argue that plaintiffs rely improperly on Dr Kiser's testimony that the claim does recite sufficient structure. Doc #68 at 11. This argument is flawed because it is defendants who have the burden, not plaintiffs. Because defendants

do not demonstrate that the claim "fails to recite sufficiently definite structure or recites a function without reciting sufficient structure for performing that function," the court need not address Dr Kiser's testimony to construe this claim.

Accordingly, the court adopts plaintiffs' proposed construction, and construes a dried non-volatile indicating element as "an immobilized indicating element that does not readily evaporate at normal temperatures and pressures and has had excess liquid removed but which may contain some water." Doc #45 at 16.

5. aqueous alkaline solution

The parties agree that "alkaline" means "a pH greater than 7." Doc #68 at 15 n8. Defendants point to several authorities that demonstrate that the term "aqueous solution," as it first appears in claim 21, is a term of art in chemistry that defines a solution where water is the primary solvent. Doc #68 at 15; Doc #60 Ex 9 at 142, Ex 10 at 37, Ex 11 at 330 Ex 12 at 28. Accordingly, the court adopts defendant's construction, and construes aqueous alkaline solution as "a solution of liquid water and one or more solutes, the solution having a pH greater than 7."

At oral argument, defendants argued that accepting their construction of "aqueous solution" requires the court to accept their construction of "aqueous indicating composition," as "functions in liquid water." Doc #68 at 12. This argument is flawed, however, because defendants fail to show that "aqueous indicating composition," is related to the term of art of "aqueous solution." Thus, the court's construction of "aqueous indicating composition" as a phrase in which the adjective "aqueous" modifies

the term "indicating composition" does not conflict with its construction of "aqueous solution" as a term of art.

6. produces a response for a second predetermined period of time longer than said first predetermined period of time when the composition is exposed only to concentrations of carbon dioxide of no more than about 0.03%

Plaintiffs contend that this limitation, first recited in claim 21, does not require a limiting construction of "the first predetermined period of time," "the second predetermined period of time" and "a response." Plaintiffs' most convincing argument rests upon the doctrine of claim differentiation. Doc #45 at 22. For example, claim 25 (a dependent claim of claim 21) requires the "second predetermined period of time" to be "longer than 10 minutes." Therefore, the "second predetermined period of time" in claim 21 must include periods other than those longer than 10 minutes.

Defendants propose a more limited construction based on the specification such that "the second predetermined period of time" is approximately ten minutes and "a response" is a false positive. Doc #60 at 26. Additionally, defendants argue that if plaintiffs' broad construction is adopted, the claim is indefinite and invalid. Doc #68 at 15-16.

Whatever the merit of defendants' invalidity argument, claim construction is a distinct issue, and the court may not import unclaimed limitations from the specification to put a saving construction on a claim. EI du Pont, 849 F2d at 1433. Accordingly, the court construes this limitation according to the plain meaning of the claim language in light of the doctrine of

claim differentiation.

IV

The '002 patent

The terms construed above for the '075 patent are identically construed for the '002 patent. Additional terms in the '002 patent also require construction. Claim 1 is illustrative:

> Apparatus for determining whether a gaseous sample contains a predetermined concentration of carbon dioxide, comprising:
>
> means for introducing the gaseous sample into an enclosure;
>
> dry reagent detector means within the enclosure for producing a response to the presence of said predetermined concentration of carbon dioxide in the sample, said detector means comprising a carrier having a aqueous indicating composition applied thereto, said indicating composition providing an indication of the presence of said predetermined concentration of carbon dioxide in the sample within a diagnostically effective period of time when the cargon dioxide concentration in the sample is at least about 2% and providing said indication after about ten minutes when the carbon dioxide concentrationin the sample is about 0.03%.

1. means for introducing the gaseous sample into an enclosure

The parties agree that this limitation should be construed under 35 USC § 112, ¶6. Doc #68 at 16. Defendants argue that the term "enclosure" should be limited to describe "a structure capable of collecting a suitable sample of gas to be tested." Doc #68 at 16. Plaintiffs seek a plain meaning interpretation, but contend that the corresponding structure "includes the enclosure depicted in figure 1 and the structure of a

double ended enclosure with openings on each end that is described at column 2, lines 25-57." Because there does not appear to be a significant disagreement between the parties, the court adopts defendant's proposal and construes the limitatation as, "the structures and materials described and illustrated in the specification for performing the function of introducing the gaseous sample into a structure capable of collecting a suitable sample of gas to be tested."

2. means responsive to said change in pH for providing an indication within a predetermined period of time of the presence of said predetermined concentration of carbon dioxide in the sample and providing said indication after about ten minutes when the concentration of carbon dioxide in the sample is substantially less than said respiratory concentration.

The parties agree that this limitation to claim 23 should be construed under 35 USC § 112, ¶6 and that the court is tasked with (1) identifying the claimed function and (2) identifying the corresponding structures disclosed in the specification for performing that function. Kemco Sales, Inc v Control Papers Co, Inc, 208 F3d 1352, 1361 (Fed Cir 2000). The court construes the function of this limitation to be (1) providing an indication within a predetermined amount of time * * * and (2) providing said indication in about 10 minutes when the concentration of carbon dioxide in the sample is substantially less than said respiratory concentration. Therefore, the structures disclosed in the specification are within the scope of this claim if, and only if, the specification adequately describes and links the structure(s) to the claimed function. Medical Instrumentation & Diagnostics Corp v Elekta AB, 344 F3d 1205, 1211 (Fed Cir 2003).

Defendants contend that the corresponding structures listed in the patent that perform this function are "water soluble indicators," which are recited in column 6, lines 56-69 of the patent. Doc #60 at 29. Plaintiffs assert that the pH indicators disclosed in column 7, lines 1-24 are the proper corresponding structures. Doc #45 at 24. Additionally, plaintiffs ask the court to consider expert testimony as to whether one skilled in the art would understand that the structures in column 7 perform the claimed function. Doc #45 at 24.

"Corresponding structure need not include all things necessary to enable the claimed invention to work. It is equally true, however, that corresponding structure must include all structure that actually performs the recited function." Cardiac Pacemakers, Inc v St Jude Medical, Inc, 296 F3d 1106, 1119 (Fed Cir 2002). Defendants argue that the corresponding structure must include a "chemical treating composition," as disclosed in column 6, lines 56-54. Defendants also ask the court to construe "means responsive to said change in pH for providing an indication * * *" to exclude the "suitable pH-sensitive indicators" recited in the specification in favor of "suitable chemical treating composition[s]." Doc #68 at 17.

It is well established that the corresponding structure to a function must actually perform the recited function, and "not merely enable the pertinent structure to operate as intended." Asyst Techs, Inc v Empak, Inc, 268 F3d 1364, 1371 (Fed Cir 2001). Thus, in order to determine whether defendants' asserted chemical compositions are corresponding structure, the inquiry is whether the chemical treating compositions enable the performance of the

claimed function within the time limitations set forth in the claim, or whether they perform it themselves.

Although Kemco Sales does assign the court -- as part of claim construction -- the task of determining which corresponding structures are associated with a means-plus-function limitation during claim construction, the court notes the pertinent inquiries regarding corresponding structures may be inherently factual and ill-suited to determination as a matter of law. Here, the issue is one of fact, namely: do the disclosed structures merely enable the claimed function to be performed or do they perform it themselves?

For this limitation, it is impossible for the court to identify the corresponding structures short of a full-blow inquiry into arguments of invalidity for lack of enablement. Patent claims are presumed valid, and "[i]nvalidity for lack of enablement is a conclusion of law [that] must be supported by facts proved by clear and convincing evidence." Northern Telecom, Inc v Datapoint Corp, 908 F2d 931, 941 (Fed Cir 1990). Accordingly, at this time, the court defers the identification of the corresponding structures by line number and instead adopts plaintiffs' construction after removing the equivalents language: "the structures and materials described and illustrated in the specification for performing the function of providing an indication within a predetermined period of time of the presence of said predetermined concentration of carbon dioxide in the sample and providing said indication after about ten minutes when the concentration of the carbon dioxide in the sample is substantially less than said respiratory concentration."

3. detector means

Claim 1 recites a "dry reagent detector means * * * for producing a response to the presence of said predetermined concentrations of carbon dioxide in the sample." Claim 24 recites "detector means * * * for responding to the presence of the predetermined concentration of carbon dioxide." The presence of the word "means" in a claim limitation creates a rebuttable presumption that the claim element should be construed under 35 USC § 112, ¶6 as a means-plus-function element. Linear Technology Corp v Impala Linear Corp, 379 F3d 1311, 1319 (Fed Cir 2004).

Plaintiffs argue that sufficient structure is recited in the language following the means-for language to overcome the presumption that § 112, ¶6 applies. Doc #45 at 24. Specifically, plaintiffs point to two phrases as denoting structure: (1) "a carrier having an aqueous indicating composition applied thereto" in claim 1; and (2) "a carrer to which a non-volatile indicating composition has been applied" in claim 24. Id.

To determine whether a term denotes sufficient structure, a court should inquire into whether "a term, as a name for the structure, has a reasonably well understood meaning in the art." Watts v XL Sys, 232 F3d 877, 881 (Fed Cir 2000). Neither party has presented evidence on whether "carrier" (claims 1 and 24) has a reasonably well understood meaning in the art that denotes structure or a class of structures. Plaintiffs point to other construed terms to argue that the indicating composition terms would denote sufficient structure to one of reasonable skill in the art. Doc #45 at 24.

Plaintiffs argue that "non-volatile indicating

composition" in claim 1 should be construed consistently with "dried non-volatile indicating element" in claim 18 of the '075 patent. But the court construes claim 18 of the '075 patent in view of the burden on defendants, whereas the construction sought by plaintiffs in claim 1 of the '002 patent places the burden on plaintiffs. The court's construction of claim 18 of the '075 patent does not establish that the term "non-volatile indicating element" was a name for a structure sufficiently well understood by those skilled in the art. And in any event, "dried non-volatile indicating element" is not the same term as "non-volatile indicating composition." By relying upon the court's construction of a claim 18 of the '075 patent in isolation, plaintiffs have not met their burden with respect to the term "non-volatile indicating composition."

"Aqueous indicating composition" is construed in claim 1 of the '075 patent as "an indicating composition containing some water." Plaintiffs rely upon this construction to overcome the presumption that "detector means" in claim 24 is a means-plus-function limitation. But the only structure supplied in this construction is "containing some water," shedding no light on whether the term "indicating composition" would denote sufficient structure to one of reasonable skill in the art. Therefore, the court finds that plaintiff has not overcome the presumption that the term "detector means" in claim 24 of the '002 patent should be construed pursuant to 35 USC § 112, ¶6.

Accordingly, the court construes the "dry reagent detector means" of claim 1 and the "detector means" of claim 24 to be limited to those structures and materials described in the '002

patent specification and figures that are disclosed as performing the plain meaning functions described in those claims, subject to the additional limitations listed in each claim.

V

Because the court has not relied upon Dr Kiser's expert declaration, the motion to strike portions of Dr Kiser's declaration (Doc #70) is TERMINATED as moot.

IT IS SO ORDERED.

VAUGHN R WALKER
United States District Chief Judge